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EXAMINER

PREBILIC, PAUL B

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/934,178
Filing Date: August 21, 2001
Appellant(s): BROWN ET AL.

James M. Urzedowski
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed March 31, 2010 appealing from the Office action mailed August 10, 2009.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

The only directly related appeal is that of parent application 08/511,076 and appeal number 1998-0022. A copy of that decision is attached to the Appellant's Appeal Brief as filed on March 31, 2010.

In the Appeal Brief filed March 31, 2010, the Appellant mentions applications related to the parent application that have had notices of appeal or appeal briefs filed therein. No decisions have yet been rendered in any of the mentioned applications.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 9, 10, 13-22 and 24-30 are currently pending and the subject of this appeal.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the Appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

5,449,373	PINCHASIK et al	09-1995
5,102,417	PALMAZ et al	04-1992
5,902,317	KLESHINSKI et al	05-1999
5,733,303	ISRAEL et al	03-1998
5,514,154	LAU et al	05-1996

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

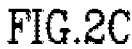
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the appellant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the appellant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 17, 20, 29 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Pinchasik et al (US 5,449,373).

Pinchasik meets the claim language where the peaks of adjacent ends of the cell are clearly offset; see Figures 2A to 2C. Each cell has two cross supports between a cell peak or valley and a band peak or valley. There are serpentine band peaks and valleys and there are cell peaks and valleys; see the figure below.



Claims 17, 20, 29 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated over Palmaz et al (US 5,102,417). Palmaz meets the claim language where the annular elements as claimed are met by the prostheses or grafts (70) of Palmaz and

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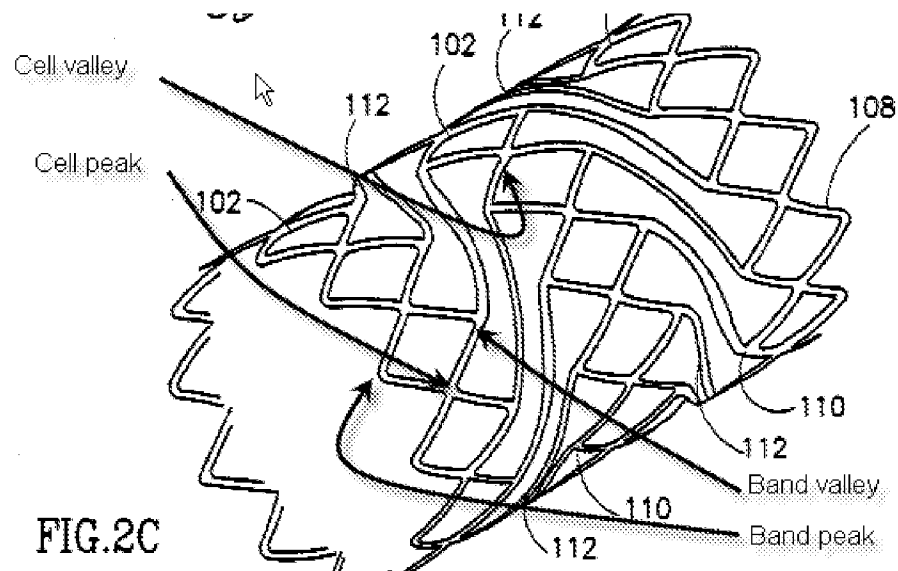
the connectors as claimed are the connectors (100) or spiral members (102) of Palmaz; see Figures 7 to 10 and column 11, line 35 et seq. The cell peaks and valleys are different from the band peaks and valleys as explained in the Pinchasik rejection *supra*. The same rationale used in the interpretation of Pinchasik rejection is utilized herein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16, 25-26 and 28 rejected under 35 U.S.C. 103(a) as being unpatentable over Pinchasik et al (US 5,449,373) in view of Kleshinski (US 5,902,317). Pinchasik meets the claim language where the peaks of adjacent ends of the cell are clearly offset; see Figures 2A to 2C. There are serpentine band peaks and valleys and there are cell peaks and valleys; see the figure below.



But Pinchasik fails to disclose a “structure” that provides the stent with less compression resistance than provided by the structure of a different annular element. However, Kleshinski teaches that it was known to put fingers on end cells in order to make them less compression resistant than other cells; see Figures 1 to 4 and column 4, lines 3-20. Therefore, it is the Examiner’s position that it would have been obvious to put fingers on the ends of the segments for the same reasons that Kleshinski does the same.

Claims 16, 25-26, and 28 rejected under 35 U.S.C. 103(a) as being unpatentable over Palmaz et al (US 5,102,417) in view of Kleshinski (US 5,902,317). Palmaz meets the claim language where the annular elements as claimed are met by the prostheses or grafts (70) of Palmaz and the connectors as claimed are the connectors (100) or spiral members (102) of Palmaz; see Figures 7 to 10 and column 11, line 35 et seq. However, Palmaz fails to disclose a “structure” that provides the stent with less compression resistance than provided by the structure of a different annular element.

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However, Kleshinski teaches that it was known to put fingers on end cells in order to make them less compression resistant than other cells; see Figures 1 to 4 and column 4, lines 3-20. Therefore, it is the Examiner's position that it would have been obvious to put fingers on the ends of the segments of Palmaz for the same reasons that Kleshinski does the same.

Claims 9, 10, 13-15, 21, 22, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Israel (US 5,733,303) in view of Pinchasik (US 5,449,372) and Kleshinski (US 5,902,317). Israel discloses a flexible expandable stent that has annular elements called meander patterns (11) and 12) and connecting members called loops (18) and (20); see Figures 1 to 4 and column 2, line 45 to column 3, line 62. Although the stent can be bent to match the curvature of the blood vessel (see Figure 3), it is not clear that the first end can be circumferentially offset from the second end.

Furthermore, although the end annular elements would be less crush resistance than the middle annular elements due to greater connector support, it is not clear that "the structure" of the end annular elements would have less compression resistance than the middle elements.

Pinchasik teaches that circumferentially offset connectors were known where similar meander pattern stents were made and as an alternative to circumferentially aligned cell ends; see Figure 2C and compare it to Figure 3C. Therefore, it is the Examiner's position that it would have been obvious to circumferentially offset the cell ends of Israel for the same reasons that Pinchasik does the same or in order to provide better coverage between stent segments.

Kleshinski teaches that it was known to have end elements with less compression resistance by putting fingers on end cells in order to make them less compression resistant than other cells; see Figures 1 to 4 and column 4, lines 3-20. The fingers have the same shape as the valley portions when the stent is compressed; see Figure 5 of Kleshinski. Furthermore, Kleshinski also teaches that it was known to lengthen cells as a means to reduce crush resistance where the cells have the same general shape; see column 4, lines 21-40 of Kleshinski. Therefore, it is the Examiner's position that it would have been considered *prima facie* obvious to an ordinary artisan to extend or elongate the end segments of Israel for the same reasons that Kleshinski does the same, that is, the reduce the radial bias at the ends of the stent.

Regarding claims 14 and 15, Israel discloses making the stents out of metal (see column 4, lines 26-31) but not of Nitinol or shape memory materials as claimed. However, Kleshinski teaches that it was known to make similar stents out of shape memory materials such as Nitinol; see column 4, lines 49-67. Therefore, it is the Examiner's position that it would have been obvious to make the stents of Israel out of Nitinol or shape memory material for the same reasons that Kleshinski teaches substituting the same.

Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palmaz (US 5,102,417) or Pinchasik et al (US 5,449,373) as applied against claim 17 above, and further in view of Lau et al (US 5,514,154). Palmaz or Pinchasik discloses making the stents out of various materials but not of Nitinol or shape memory materials as claimed. However, Lau teaches that it was known to make similar stents

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out of Nitinol (Nitinol is a NiTi alloy with shape memory properties) or shape memory material as an alternative to balloon expandable stents; see column 2, lines 12-56 and the paragraph bridging columns 6 and 7. Therefore, it is the Examiner's position that it would have been obvious to make the stents of Palmaz or Pinchasik out of Nitinol or shape memory material for the same reasons that Lau teaches substituting the same.

(10) Response to Argument

Issue 1

On page 14 of the Appeal Brief filed March 31, 2010, the Appellant argues that cells must be defined by connectors bounding them; the Examiner asserts that there is nothing in the claim language that precludes the cells from having cross supports. Furthermore, since the meaning of "cell" has no special definition in the present specification, and has only been used in an exemplary fashion, it can be given its broadest ordinary and reasonable interpretation. In particular, the only usage of "cell" is provided by the specification insertion made to page 4 stating that "[i]nterconnecting elements 20 and adjacent segment 16 form a plurality of cells 24 that change shape upon expansion of the stent." **It should be noted that the present disclosure did not even contain the term "cell" until it was added to the specification on May 28, 2003, that is, about 2 years after the present application was filed and about 8 years after the parent application was filed.** Openings in stents are called by numerous terms within the art such as cells, openings, apertures, holes, etc. For this reason, since cells are only exemplified as bounded by interconnecting elements,

Pinchasik meets the claim language in the openings in the segments (102) are not bounded by interconnecting elements so they are not cells.

The Appellant argues that a "cell" is denoted by "a small compartment or bounded space" and thus, the diamond openings of Pinchasik and Palmaz must be cells. However, the Examiner asserts that since the art utilizes various terms for bounded spaces in stents, it is reasonable to call some of the bounded species (i.e., the diamond shaped spaces) "openings", "apertures", or "holes." For this reason, the claim language is considered fully met by that disclosed by Pinchasik or Palmaz.

On page 15 of the brief, the Appellant argues that Pinchasik does not disclose "serpentine bands." However, the Examiner asserts that the serpentine bands are clearly present by inspection of the drawings. Furthermore, "*serpentine*" means merely *"1: of or resembling a serpent (as in a form or movement), 2: subtly wily or tempting, 3a: winding or turning one way and another <a serpentine road> b: having a compound curve whose central curve is convex."* (Merriam-Webster OnLine located at http://www.merriam-webster.com/dictionary/serpentine_) Clearly, each of the segments (102) of Pinchasik et al or prostheses (70) of Palmaz has a structure that falls within this definition.

The Appellant also argues that the limitations of claim 30 are not met. However, it is clear when viewing the annotated figure of the corresponding rejection above that some of the peaks and valleys are not connected to a connecting member, at least not directly as is the case with the disclosed stent. For this reason, the lack of direct

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connection of the peaks and valleys is as present in Pinchasik or Palmaz as it is present in the disclosed invention.

Issue 2

The Appellant's traversal of the Palmaz rejection was sufficiently addressed in the Issue 1 section supra. For the reasons set forth in the Issue 1 section of this Examiner's Answer, the claims are not considered patentable over Palmaz.

Issue 3

The Appellant's traversal of the Pinchasik et al in view of Kleshinski et al rejection was sufficiently addressed in the Issue 1 section supra. The Appellant has relied upon the arguments made in the corresponding section of the brief to traverse this ground. For the reasons set forth in the Issue 1 section of this Examiner's Answer, the claims are not patentable over Pinchasik et al in view of Kleshinski et al.

Issue 4

The Appellant's traversal of the Palmaz et al in view of Kleshinski et al rejection was sufficiently addressed in the Issue 1 section supra. The Appellant has relied upon the arguments made in the corresponding section of the brief to traverse this ground. For the reasons set forth in the Issue 1 section of this Examiner's Answer, the claims are not patentable over Palmaz et al in view of Kleshinski et al.

Issue 5

In traversing the Issue 5 rejection, the Appellant argues that Israel et al teaches against the helical connectors of Pinchasik et al because it says that, upon expansion, "the twisting motion is most probably harmful to the blood vessel." However, it is noted that the Pinchasik et al stent or graft is markedly different from the Palmaz et al stent because it has much longer connectors relative to the diameter of the stent. Furthermore, the expanded form of the Pinchasik et al stent is shown in Figure 2C as being smooth not visibly twisted. Finally, there is no evidence supporting this allegation by Israel et al so it is mere speculation. Moreover, the figures of Pinchasik et al provide sufficient evidence of utility, operability and functionality provide such that there is sufficient motivation to modify Israel et al as suggested. In fact, the very modification proposed by the rejection is suggested by the alternative embodiments of Pinchasik et al when comparing Figure 2C to Figure 3C. For these reasons, the statement of Israel is considered insufficient evidence that Israel et al teaches away from the proposed combination; see MPEP 2123 that is incorporated herein by reference

With regard to the traversal of the teaching of Kleshinski, the examiner previously added further explanations as to how the claim language is being interpreted. For example, the fingers have the same shape as the valley portions when the stent is compressed; see Figure 5 of Kleshinski. Furthermore, Kleshinski also teaches that it was known to lengthen cells as a means to reduce crush resistance where the cells have the same general shape; see column 4, lines 21-40 of Kleshinski. Therefore, it is the Examiner reasons that it would have been considered *prima facie* obvious to extend

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or elongate the end segments of Israel et al for the same reasons that Kleshinski does the same, that is, to reduce the radial bias at the ends of the stent.

Issue 6

The Appellant's traversal of the Pinchasik et al or Palmaz et al in view of Lau et al rejection was sufficiently addressed in the Issue 1 section supra. The Appellant has relied upon the arguments made in the corresponding section of the brief to traverse this ground. For the reasons set forth in the Issue 1 section of this Examiner's Answer, the claims are not patentable over Pinchasik et al or Palmaz in view of Lau et al.

(11) Related Proceeding(s) Appendix

Copies of the court or Board decision(s) identified in the Related Appeals and Interferences section of this examiner's answer are provided in the Appellant's Brief filed March 31, 2010.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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Primary Examiner, Art Unit 3774

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